K946170

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# 10(k) Summary of Safety and Effectiveness in Accordance with SMDA'90

B. Braun of America, Inc

December 16, 1994

Twelfth
Bethlehem, PA 18018
(215)691-5400

CONTACT: Mary S. Alsberge, Regulatory Affairs Associate

PRODUCT NAME: Subcutaneous Injection Sets

TRADE NAME: Comfort-Q Subcutaneous Injection Sets

CLASSIFICATION NAME:

General Hospital
Class II 880 FPA, Intravascular Administration Set
21 CFR 880.5440

SUBSTANTIAL EQUIVALENCE TO

| 510(k) number | Name | Applicant |
|---|---|---|
| K801941 | MICROCATH INTRAVENOUS CATHETER PLACEMENT UNIT AND CATHETER | BURRON MEDICAL INC. |
| K873885 | SUBCUTANEOUS INFUSION SET | PHARMACIA DELTEC |

DEVICE DESCRIPTION:

B. Braun of America Inc. intends to introduce into interstate commerce the Comfort-Q Subcutaneous Injection Sets. The Comfort-Q Subcutaneous Injection set is a 23 gauge 3/8 in. (0.9cm.) catheter over 26 gauge intorducer needle with 42 in. (106.7cm.) microbore tubing. Adhesive dressing is enclosed. These all have similar designs and per for mance characteristics. The intended use for administration of fluids or other therapeutic agents subcutaneously.

ATTACHMENT 2

TERIAL :

B. Braun of America certifies that the biocompatibilty tests recommended in the Tripartite Guidance for this category of contact duration will be completed for all the materials listed above for use in the manufacture of the device. All the materials listed above have also past requirements for USP Class 6, cytotoxicity, Hemolysis, and USP Physio-chemical testing.

BST'ANTIAL EQUIVALENCE:

From a regulatory standpoint, the Comfort-Q Subcutaneous Injection Sets are equivalent in materials, form, and intended use to the Pharmacia Deltec (Subcutaneous Infusion Sets) and in materials to the Burron Medical, Inc. (Microcath Intravenous Catheter and Placement Unit and Catheter). There are no new issues of safety or effectiveness raised by the Comfort-Q Subcutaneous Injection Sets.

AFETY AND EFFECTIVENESS:

All finished products are tested and nust meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; sterility, pyrogenicity (endotoxin/ LAL Method), physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Produre documents. These tests are established testing procedures and parameters which conform to the product design specifications. The physical testing for the The Comfort-Q Subcutaneous Injection Sets is defined in detail in the "Device Master Records".

The testing instruction records for each of the individually required procedures are approved, released, distributed and revise in accordance with document control GMP"s.

ATTACHMENT 2

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